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PATENT & TRADEMARK OFFICE

Attorney Docket No.:
AVSI-0009 (108328.00031)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Robert Schwartz, et al.,
Serial No.:	10/021,403
Filed:	12/12/2001
For:	**ADMINISTRATION OF NUCLEIC ACID SEQUENCE TO FEMALE ANIMAL TO ENHANCE GROWTH IN OFFSPRING**
Group No.:	1632
Examiner:	Dr. Joanne Hama

Mail Stop AF
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

CERTIFICATE OF MAILING: I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on 5-22-06

Tracy E. Giroux
(Printed or typed name of person signing the certificate)

Tracy E. Giroux
(Signature of the person signing the certificate)

DECLARATION UNDER 37 C.F.R. § 1.132

Ruxandra Draghia-Akli declares that:

1. I am a co-inventor of, and familiar with, the present U.S. Patent Application Serial No. 10/021,403, filed December 12, 2001, in the name of Robert Schwartz, and entitled "ADMINISTRATION OF NUCLEIC ACID SEQUENCE TO FEMALE ANIMAL TO ENHANCE

GROWTH IN OFFSPRING," ("the '403 Application"). I am also familiar with the Final Official Action dated February 23, 2006 issued therein.

2. I am over 21 years old. I graduated from "Ion Luca Caragiale" Lyceum, Bucharest, Romania, in 1983 with a degree in Mathematics and Physics. I then graduated from "Carol Davilla" Medical School, Bucharest, Romania in 1989 with an M.D. degree, and the M.D. thesis was in the field of Cardiology. I received my Ph.D. degree from the Romanian Academy of Medical Sciences, Bucharest, Romania with a fellowship at the University "Rene Descartes" (Paris V) in Paris, France, in 1994, with a major in Human Genetics and a heavy concentration in courses on lysosomal diseases. My Ph.D. thesis was in the field of lysosomal diseases and gene therapy. I completed a postdoctoral fellowship (1995-1997) in the Department of Molecular and Cellular Biology at Baylor College of Medicine, Houston, Texas, USA.

3. In 1997, I became faculty with a dual appointment in the Department of Molecular and Cellular Biology and in the Center for Cell and Gene Therapy at Baylor College of Medicine, Houston, Texas, USA. I was an Assistant Professor in the Department of Molecular and Cellular Biology and in the Center for Cell and Gene Therapy at Baylor College of Medicine, Houston, Texas, USA until March 2002. From March 2002 until present, I have worked as the Vice President of Research at ADViSYS, Inc., The Woodlands, Texas, USA. In this latest position, my responsibilities are as following: a) engage in research and development in support of veterinary and human pre-clinical and clinical trials and other studies for the development of the company's products, and the research and development involve numerous animal species (from rodents to non-human primates); b) oversee the daily operations of the company's research program and the entire research team; c) provide key leadership in discovering and designing new products for the company's product portfolio; d) work with manufacturing personnel to scale up research and commercial GMP and GLP products; e) work with regulatory group to comply with federal agencies rules and regulations, and product approval for commercialization; and f) work with intellectual property attorneys to prepare, file, and prosecute patent applications.

4. I personally prepared and conducted the examples described in the '403 Application..

5. The descriptions and teaching of the '403 Application provide sufficient guidance for any person of skill in the art to enhance the growth of offspring in farm animals. The amount of experimentation required would be well within the accepted amount in this field.

6. After 2001, I personally prepared and conducted further examples using methods and compositions described in the '403 Application in various other mammalian species. Using the same methods and techniques described in the '403 application, we have replicated the experiments in dairy and beef cattle, and start preliminary studies in sheep. The results of the experiments showed that:

a) plasmid delivery by the method and technique described in the '403 application can be applied without any further elaborate experimentation in mammalian species;

b) plasmid-mediated GHRH supplementation given to pregnant mammals in the last third part of their gestation resulted in improved or enhanced growth in their offspring, with better maternal health, as well as reduced morbidity and mortality in the treated animals and their offspring. Further studies reveled that the plasmid does not cross the placenta, and it is not present in the amniotic fluid, colostrums or milk, thus the conclusion is that the plasmid does NOT cross to the offspring. I have attached color copies of a set of slide presentations as Exhibit A; and

c) other workers have been able to replicate our experience without our participating at the treatment, data recording or analysis.

7. I have personal knowledge of persons having ordinary skill in the art and, who were not associated with the inventors of the '403 Application, utilized the methods and compositions of the claimed subject matter with the desired results in other mammalian species. For instance, a large commercial entity used the treatments on a large number of pregnant sows, and collected the information regarding the offspring (thousands of animals involved in the studies). They statistically analyzed and confirmed our findings regarding growth, body composition, morbidity and mortality;

and furthermore noticed that the changes were within normal physiological variation for the given species.

8. To the best of my knowledge, the placental barrier cannot be crossed by nucleic acid encoding a growth hormone releasing hormone ("GHRH") molecule that is injected into the muscle of a pregnant female animal according to the described method of the '403 Application. Moreover, once a person of ordinary skill in the art knows that a pregnant mother can be treated with the GHRH composition, it is a purely routine procedure to analyze any expected or unexpected results arising from GHRH originating from different species.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Draghia-S

Ruxandra Draghia-Akli, M.D., Ph.D.

May 22, 2006

Date